

June 22, 2020 Supersedes February 4, 2020

Records of Formulation for Marijuana Products Intended for Inhalation

The intent of this technical bulletin is to publish information in accordance with the administrative rules.

Rule 6(12) in the Marijuana Operations Rule Set – R 420.206(12)

A marijuana business producing marijuana products shall maintain records of formulation and make them available to the agency upon request.

Rule 6(11) in the Marijuana Operations Rule Set – R 420.206(11)

All non-marijuana inactive ingredients must be clearly listed on the product label. Inactive ingredients, other than botanically derived terpenes that are chemically identical to the terpenes derived from the plant *Cannabis Sativa L.*, must be approved by the FDA for the intended use and the concentration must be less than the maximum concentration listed in the FDA Inactive Ingredient database for the intended use.

Rule 1(o) in the Marijuana Operations Rule Set – R 420.201(o)

"Inactive ingredients" means binding materials, dyes, preservatives, flavoring agents, and any other ingredient that is not derived from the plant *Cannabis Sativa L*.

For marijuana products intended for inhalation:

The Records of Formulation do not need to be submitted to the Marijuana Regulatory Agency (MRA) for review or approval prior to creation of the product, however, it must be filled out in its entirety for every line of vape product that the producer chooses to produce. The MRA reserves the right to request a copy of the Record of Formulation at any time as outlined in Rule 6(12) in the Marijuana Operations Rule Set - R 420.206(12).

https://www.michigan.gov/documents/mra/22 Record of Formulation 711231 7.pdf

Note: Effective March 1, 2020 medical growers and processors can only obtain bud, shake, and trim from caregivers.



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Source Oil (Regulated Market), Terpenes (Regulated Market)



- •Source Oil: Plants are grown by a licensed processor or sourced from the external market, but processed entirely in the regulated market.
- •**Terpenes**: Created through distillation/separation process from the marijuana plants used to create the source oil by a licensed processor.

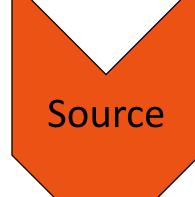


- •Source Oil: Retain a detailed standard operating procedure (SOP) outlining the extraction process as well as the cartridge filling process. Remember to document metrc tags as well as certificates of analysis (COAs) for any vape carts used during the process to ensure chain of custody
- •**Terpenes**: Include all information for the processing of marijuana flower into oil and terpenes, including any separation and recombination of products.
- •Record of Formulation should be stored with all other documentation for each line or brand of vape cartridges produced at the licensed processing facility.
- •Vitamin E Acetate testing in final state <u>is required</u> in addition to full compliance testing.

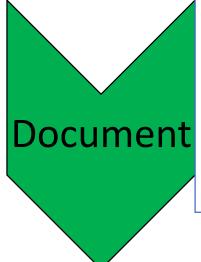


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Source Oil (Regulated Market), Terpenes (External Market)



- •Source Oil: Plants are grown by a licensed processor or sourced from the external market, but processed entirely in the regulated market.
- •**Terpenes**: Sourced from the external market; either caregiver (prior to the March 1, 2020 cutoff date) OR from a certified vendor of botanical terpenes.

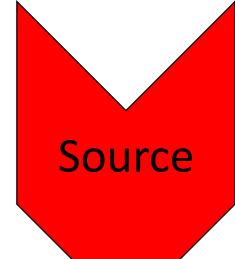


- Source Oil: Retain a detailed SOP outlining the complete extraction process as well as the cartridge filling process.
 Remember to document metrc tags as well as COAs for any vape carts used during the process to ensure chain of custody
- •**Terpenes**: Name the vendor and keep records of all invoices, COAs and safety data sheets (SDS). Remember to keep a log of all strain/flavors sourced from any vendor.
- •Vitamin E Acetate testing in final state <u>is required</u> in addition to full compliance testing.

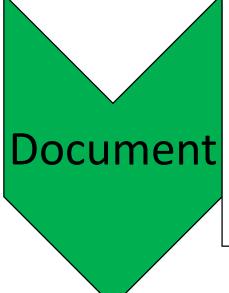


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Source Oil (External Market), Terpenes (External Market)



- •Source Oil: Sourced from the external market; either caregiver (prior to the March 1, 2020 cutoff date).
- •**Terpenes**: Sourced from the external market; either caregiver (prior to the March 1, 2020 cutoff date) OR from a certified vendor of botanical terpenes.



- •Source Oil: Retain all records and patient numbers related to the licensed caregiver or facility from which the oil was originally obtained. Retain an SOP outlining the cartridge filling process. Remember to document metrc tags as well as COAs for any vape carts used during the process to ensure chain of custody
- •Terpenes: Name the vendor and keep records of all invoices, COA and SDS. Remember to keep a log of all strain/flavors sourced from any vendor.
- •Vitamin E Acetate testing in final state <u>is required</u> in addition to full compliance testing.